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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------|------------------|
| 10/780,378  | 02/17/2004  | Jeff Blaylock        | ZIM0356                   | 1826             |
| 7590 03/30/2007  John F. Hoffman, Esq.  BAKER & DANIELS LLP |             |                      | EXAMINER PREBILIC, PAUL B |                  |
| Suite 800   |             | ART UNIT             | PAPER NUMBER              |                  |
| 111 East Wayn<br>Fort Wayne, IN                             |             |                      | 3738                      |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE                      |             | MAIL DATE            | DELIVERY MODE             |                  |
| 3 MONTHS  |             | 03/30/2007           | PAPER                     |                  |

# Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|   |  | Application No.  | Applicant(s)    |  |  |  |  |
|---|--|------------------|-----------------|--|--|--|--|
| Office Action Summary   |  | 10/780,378       | BLAYLOCK ET AL. |  |  |  |  |
|   |  | Examiner         | Art Unit        |  |  |  |  |
|   |  | Paul B. Prebilic | 3738            |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |  |                  |                 |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                  |                 |  |  |  |  |
| Status  |  |                  |                 |  |  |  |  |
| 1) Responsive to communication  | Responsive to communication(s) filed on <u>08 January 2007</u> .   |                  |                 |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> .   | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.   |                  |                 |  |  |  |  |
|   | ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |                  |                 |  |  |  |  |
| closed in accordance with   | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |                  |                 |  |  |  |  |
| Disposition of Claims   |  |                  |                 |  |  |  |  |
| 4a) Of the above claim(s) 2 5) ☐ Claim(s) is/are allow 6) ☒ Claim(s) 1-19,24 and 25 is 7) ☐ Claim(s) is/are objective.  | 4)  Claim(s) 1-55 is/are pending in the application.  4a) Of the above claim(s) 20-23 and 26-55 is/are withdrawn from consideration.  5)  Claim(s) is/are allowed.  6)  Claim(s) 1-19,24 and 25 is/are rejected.  7)  Claim(s) is/are objected to.  8)  Claim(s) are subject to restriction and/or election requirement. |                  |                 |  |  |  |  |
| Application Papers  | ·  |                  |                 |  |  |  |  |
| <ul> <li>9) ☐ The specification is objected to by the Examiner.</li> <li>10) ☑ The drawing(s) filed on 17 February 2004 is/are: a) ☑ accepted or b) ☐ objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>  |  |                  |                 |  |  |  |  |
| Priority under 35 U.S.C. § 119  |  |                  |                 |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |  |                  |                 |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawin   |  | 4)               |                 |  |  |  |  |
| 5) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2/17/04.  5) Notice of Informal Patent Application 6) Other:   |  |                  |                 |  |  |  |  |

#### Election/Restrictions

Claims 20-23 and 26-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the replies filed on December 4, 2006 and on January 8, 2007. Although Species C is not explicitly stated as being the elected species (see the January 8, 2007 response), Applicants' statement "drawn to provisional augments and holders" is understood to implicitly elect Species C.

### Claim Objections

Claims 15-17 are objected to because of the following informalities: The last lines of each of claims 15 to 17 is grammatically awkward or incomplete in that the adjective "provisional" does not have a corresponding noun that it modifies. To overcome this objection, the Examiner suggests changing "provisional" to ---provisional augment.---

Appropriate correction is required.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, and 8-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Noiles (US 4,790,852). Noiles anticipates the claim language where the annular

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member as claimed is the sleeve of Noiles, the outer lateral surface as claimed is the portion (34), and the outer posterior surface as claimed is one of the flat surfaces on portion (8); see Figures 1, 3, and 8 as well as column 4, line 5 et seq.

With regard to claim 4, the reduced thickness as claimed has the thickness of zero millimeters at slot (26).

With regard to claim 9, the Applicants are directed to column 4, lines 55-65.

With regard to claims 8 and 10, the flat portion does not taper so it has a zero degree taper, and thus, falls within the claimed range.

With regard to claim 11, the Applicants are directed to Figure 2.

With regard to claim 13, the Examiner notes that one flat surface of portion (8) is closer to one curved lateral or medial portion than it is to the other lateral or medial curved portion. For this reason, the claim language is considered fully met.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Noiles (US 4,790,852) alone. Noiles meets the claim language except does not have grooves but has slots instead. However, the Examiner asserts that replacing slots with grooves would have been obvious to an ordinary artisan because a groove would function in an identical or at least very similar way as a slot.

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Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Noiles (US 4,790,852) in view of Ferree (US 6,981,991). The effective filing date for this claim is considered to be February 17, 2004 because the subject matter of this claim was added to the specification at that time. Noiles meets the claim language as explained in the Section 102 rejection, but Noiles fails to disclose a reduced thickness portion of a finite thickness as claimed. However, Ferree teaches that it was known to utilize a reduced thickness portion in order to prevent rotation of the stem; see Figure 7 and column 2, lines 6-7. Therefore, it is the Examiner's position that it would have been obvious to place a finite thickness reduced thickness portion in addition to or in place of the slot (26) of Noiles as a means to prevent rotation of the stem as taught by Ferree.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Noiles (US 4,790,852) in view of Johnson et al (US 6,136,029). Noiles meets the claim language as explained in the Section 102 rejection supra but fails to disclose the utilization of porous tantalum as the implant material. However, Johnson teaches that it was known to use porous tantalum in the art; see column 4, lines 42-58. Therefore, it is the Examiner's position that it would have been obvious to utilize porous tantalum as the implant material for the same reasons that Johnson utilizes the same.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Noiles (US 4,790,852) in view of Lawson (US 6,074,423). Noiles meets the claim language as explained in the Section 102 rejection supra but fails to disclose making the sleeve out of transparent material. However, Lawson teaches that it was known to the art to make implants X-ray transparent in order to assess the progress of bone healing after

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implantation; see the paragraph bridging columns 5 and 6. Therefore, it is the Examiner's position that it would have been obvious to make the Noiles implant X-ray transparent for the same reasons that Lawson does the same.

Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noiles (US 4,790,852) in view of Krstic (US 2003/0183025). Noiles meets the claim language as explained in the Section 102 rejection supra, or renders the claim language obvious as explained in the Section 103 rejection of claim 17 supra, but fails to disclose the use of photo-elastic material therewith as claimed. However, Krstic teaches that it was known to make body insertable materials out of photo-elastic material in order to test or measure the stresses thereon upon implantation; see the abstract and paragraph [0042]. Therefore, it is the Examiner's position that it would have been obvious to utilize a photo-elastic material in the Noiles device in order to test bone stresses on the device as taught by Krstic.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Bolesky (US 4,822,366). Bolesky anticipates the claim language where a plurality of differently-sized augments is disclosed; see Figures 2 and 6 as well as column 6, lines 35-54.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolesky (US 4,822,366) in view of Lawson (US 6,074,423). Bolesky meets the claim language as explain in the Section 102 rejection of the previous paragraph but fails to make the implant transparent as claimed. However, Lawson teaches that it was known to the art to make implants X-ray transparent in order to assess the progress of bone healing after implantation; see the paragraph bridging columns 5 and 6.

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Therefore, it is the Examiner's position that it would have been obvious to make the Bolesky implant X-ray transparent for the same reasons that Lawson does the same.

With regard to claim 25, the handle, or part of it, is shown in Figure 8 of Bolesky as a bolt that holds the pieces together and facilitates removal as one piece. The bolt has ribs in the form of threads that fit in the grooves of the implant. The sizes vary with the sizes of the implant as explained on column 6, lines 35-54 of Bolesky.

#### Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul B. Prebilic Primary Examiner